APPEAL BRIEF FOR PATENT APPLICATION NO. 10/729,725

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Art Unit: 3739
John Paul Weirich	Examiner: Matthew J. Kasztejna
Serial No.: 10/729,725	Tel: (571) 272-6086
Filed: December 4, 2003	Office Action: 01/16/2007
For: Capsule Imaging System	Confirmation No.: 4004
Appn. No. 10/729,725	

CERTIFICATE OF FAXING OR MAILING

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Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dated: May 5, 2007 Signed: John Paul Weirich

John Paul Weirich

RESPONSE TO FINAL REJECTION UNDER 35 USC §103

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This enclosed "Appeal Brief" is responsive to the Office communication mailing date January 16, 2007, which is a Rejection of Claims of my amended patent application number 10/729,725 filed on December 4, 2003.

PTO/SB/17 (05-07)
Approved for use through 05/31/2007. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Effective on 12/08/2004.
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL
For FY 2007

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	250

Complete if Known	
Application Number	10/729,725
Filing Date	12/04/2003
First Named Inventor	JOHN PAUL WEIRICH
Examiner Name	KASZTEJNA, MATTHEW JOHN
Art Unit	3739
Attorney Docket No.	

METHOD OF PAYMENT (check all that apply)

☑ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☐ Deposit Account Deposit Account Number: _____ Deposit Account Name: _____

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, **except for the filing fee**

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WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

FEE CALCULATION

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 20 or HP =	_____	x _____	= _____

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims	Extra Claims	Fee ($)	Fee Paid ($)
_____ - 3 or HP =	_____	x _____	= _____

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($)	Multiple Dependent Claims Fee Paid ($)
_____	_____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee ($)	Fee Paid ($)
_____ - 100 =	_____	/ 50 = _____ (round **up** to a whole number)	x _____	= _____

4. OTHER FEE(S)

	Fees Paid ($)
Non-English Specification, $130 fee (no small entity discount)	
Other (e.g., late filing surcharge): Appeal Brief	250

SUBMITTED BY

Signature		Registration No. (Attorney/Agent)	Telephone 650-857-0871
Name (Print/Type)	JOHN WEIRICH		Date 05/15/2007

AF/IAW

PTO/SB/21 (04-07)
Approved for use through 09/30/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	10/729,725
Filing Date	12/04/2003
First Named Inventor	JOHN PAUL WEIRICH
Art Unit	3739
Examiner Name	KASZTEJNA, MATTHEW JOHN
Attorney Docket Number	

Total Number of Pages in This Submission

ENCLOSURES *(Check all that apply)*

- [✓] Fee Transmittal Form
- [X] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s) _____
  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [✓] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [✓] Other Enclosure(s) (please Identify below):

Remarks

COPY OF PATENTS 5,841,126; 2,788,390; 3,371,362; 7,061,523 B2; 5,668,555; 2003/0085994 A1.

COPY OF OFFICE ACTION.

~~Fee attached~~

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name			
Signature	John Paul Weirich		
Printed name	JOHN WEIRICH		
Date	05/14/2007	Reg. No.	

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature	John Weirich		
Typed or printed name	JOHN WEIRICH	Date	05/15/2007

APPEAL BRIEF FOR PATENT APPLICATION NO. 10/729,725

Table of Contents

(i)REAL PARTY IN INTEREST

The real party in interest is John Paul Weirich the inventor.

(ii) RELATED APPEALS AND INTERFERENCES

None.

(iii)STATUS OF CLAIMS

Claims 1-20 are canceled.

Claim 21 is twice rejected and appealed here.

Claim 22 is twice rejected and appealed here.

Claim 23 is twice rejected and appealed here.

Claim 24 is twice rejected and appealed here.

Claim 25 is twice rejected and appealed here.

Claim 26 is twice rejected and appealed here.

Claim 27 is twice rejected and appealed here.

Claim 28 is twice rejected and appealed here.

(iv)STATUS OF AMENDMENTS

None.

(v)SUMMARY OF CLAIMED SUBJECT MATTER

In a preferred embodiment, the present invention comprises an UWB imaging sensor enclosed within a capsule powered by a battery and able to communicate with a receiver outside the body of the subject by means of a transmitter, as described on page 1 paragraphs [0013] and [0014] of US Patent Application Publication No. US 2004/0152988.

Paragraph [0020] on page 2 describes the vest-style receiver system to be worn by the subject. FIG 4 shows this vest-style receiving system, which simply receives the signals transmitted from the capsule as detailed in paragraph [0040] on page 3.

FIG 2 illustrates the details of the components of the UWB capsule imager. Here the UWB sensor 12, is connected to the controlling circuitry 14, tranceiver 16, battery 18, and antennae10 and 20. These details are in paragraph [0033] on page 2.

UWB imaging is distinguished from visible light imaging in many ways, one being its ability to penetrate through tissues and "see below the surface" to image hidden features as pointed out in paragraph [0009] on page 1. Further, the miniaturization of UWB circuitry finally enabled it to be enclosed in a swallowable capsule, paragraph [0010] also on page 1.

(vi)GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The examiner rejects all claims 21-28 on the basis of obviousness as stated in 35 USC 103(a). The examiner states the invention is unpatentable in light of US Patent Application No. 2003/0085994 to Fujita et al., in view of US Patent No. 5,668,555 to Starr. Whether claims 21-28 are obvious under 35 USC 103(a) is what is being determined in this case.

Examiner argues that Fujita et al. disclose a capsule imaging system that uses visible light signals above 3 Ghz (paragraphs 0051-52, 0063, and 0098). Examiner further argues that combining the teachings of Starr's ultra-wideband biological tissue imaging system, with the teaching from Fujita et al., would be obvious to some skilled in the art at the time of invention.

(vii)ARGUMENT

Rejection under 35 USC 103(a)

Important Note 1

The USPTO carefully examined and granted claims 1, 2, and 3 in the Fujita et al. US Patent No 7,061,523. These claims describe a visible light capsule endoscopy device. In this case Fujita et al. simply substitute a CMOS visible light sensor for the temperature sensor described in Pope's capsule device US Patent No. 3,971,362 (abstract), as taught in Sheldon's endoscopy device equipped with a video camera US Patent No. 2,788,390 (column 1 and Fig. 4) combined with the teaching from Fossum et al.US Patent No. 5,841,126 to use a CMOS sensor for medical imaging (paragraph 1, Background and Summary of the Invention). Said another way, Fujita et al. changed the frequency of the sensor being used for the detection of "living body tissue information", from infrared to visible light, and were correctly granted patent rights for this invention by the USPTO following thoughtful critical judgment of the issues.

It is helpful to know that ultimately the USPTO will apply similar rules of judgment in this case. In this case the frequency of the sensor is similarly changed from the visible light spectrum to the UWB spectrum. Differently, the fact that many different frequencies are used (ultra-wideband) results in the ability to penetrate

tissues and image characteristics "unseen" by visible light. Therefore this, the UWB approach to imaging, is a novel and big improvement for subjects as it will enable detection of diseased tissues in the gastro-intestinal system that would not otherwise be found by simple visual inspection.

See the document "Ultra-Wideband Radar Methods and Techniques of Sensing and Imaging" in the Evidence Appendix (section ix) Introduction and sections 1.1 and 1.2 on pages 1 and 2 for the basics of how UWB imaging works and how it is fundamentally different from visual light imaging.

Claim 21

In regards to claims 21 examiner states that Fujita et al. disclose a capsule imaging system that uses the electromagnetic wave spectrum above three gigahertz. This is true, however Fujita et al. are using the visible light portion of the spectrum, not an ultra-wideband (UWB) sensor as claimed; this is the notable difference in imaging means which distinguishes the present invention from Fujita's et al.

Using an UWB sensor as an imaging means is fundamentally different from using visible light imaging. Regulations require that UWB medical imaging devices operate below 1 gigahertz (Ghz) or between 3.1 to 10.6 Ghz, and at a very low power level.

At the time the present invention was, in 2003 , UWB imaging apparatus and devices were very large and UWB circuitry was certainly not sized at the microchip scale. At that time UWB imaging devices were very large, like the device patented by Starr. Thus the juxtaposition of a large UWB imaging device with a small capsule device is not natural or obvious. It is, in fact, a natural non-sequator.

Further, the visible light capsule endoscopy devices like that described by Fujita et al. and those from Given Imaging were likely considered to be wholly adequate to meet the needs of the medical imaging market. It would never have, and indeed didn't, enter the minds of anyone until the present invention in 203.

A worldwide search of the literature was done by a licensed patent attorney before the patent application for the present invention was even started, obviously to save time and money in case anyone else had thought of it. There was absolutely no mention of an UWB capsule imaging endoscopy device by anyone anywhere at that time, and in fact, even now no-one says that there was. Clearly this idea did not occur to anyone prior to this invention, because it is not obvious.

Please note that the Fujita et al. patent claims many other types of sensors

besides visible light sensors, and even claims the use of an UWB radio for communication means. Therefore it is clear that Fujita et al. were fully aware of UWB technology at the time they made their invention. Nevertheless, they did not claim an UWB imaging sensor, even though all they had to do was add one additional claim, to the several dozen others, in their patent application to cover it.

Fujita et al. were skilled in the art of UWB technology in 2003, yet it never occurred to them to claim an UWB sensor for their device. This proves that the present invention is not obvious to those skilled in the art, as currently held by the examiner.

Additionally, claim 1 refers to the radio spectrum above 1 Ghz not 3 Ghz.

Claim 27

Claim 27 substitutes a transceiver for the transmitter means of claim 21, and so should be granted along with claim 21.

Claim 22

Here the imaging means is an UWB imaging sensor operating above 3 Ghz. To reinforce here the points made above, using UWB is fundamentally different from using visible light because UWB can pass beyond the gastro-intestinal

mucosa to detect things "beneath the surface" that cannot be seen using visible light.

Fujita et al. does not mention use of an UWB imaging sensor, although they do describe and were granted claims for all other obvious types of sensors for their capsule endoscopy device, which is just like Pope's temperature capsule sensor except it uses a different frequency.

Claims 22-25

These claims provide additional limiting details of the device described in claim 22, so should therefore be approved with claim 22.

Claim 26

The subject being imaged should have a signal receiver attached for easy carrying.

Claim 28

Claim 28 substitutes a transceiver for the transmitter means of claim 22, and so should be granted along with claim 22.

Important Note 2

Therefore, to conclude, I respectfully ask you to reconsider and grant all the

claims 21-28 of the present invention that uses an UWB sensor for imaging means, which is a novel and true improvement relative to the visible light technology commonly used when the invention was in 2003. "Seeing beneath the surface" will allow the detection of many deadly tumors and tissues that would not be found by simply examining the surface of the mucosa using visible light.

Obviousness is a subjective decision and it cannot be disproven since it is in the eye of the beholder. The approach here is to point out that people with complete knowledge of both UWB and capsule endoscopy technologies did not utter a single word to anyone anywhere at any time, before the present invention was in 2003. Therefore it was not an obvious combination.

For the health of the US economy it is important that small enterprises invent new technologies that are then acquired and marketed by large enterprises. It is important that patent protection be granted to these novel technologies to serve the larger economy for all citizens, otherwise no-one will invest the time and money in creating new technology.

The claims being appealed here were mainly written by a licensed patent attorney with over a dozen years experience, with just a few small edits by the appellant. This appeal is wholly written by the appellant.

(viii)CLAIMS APPENDIX

1. (canceled): An imaging system comprising:

a swallowable capsule comprising:

an ultra-wideband radar sensor system for imaging objects; and

controlling circuitry means that operatively regulates said imaging system; and

a transceiver to transmit imaging signals of said ultra-wideband radar sensor system and to receive controlling signals; and

a power supply for said imaging system.

2. (canceled): A system according to claim 1 and including a miniature communications port wherein the electrical circuitry within said capsule is connected through the capsule wall to electrical contacts located on the outside surface of the capsule wall.

3. (canceled): A system according to claim 1, and alternative claim 2, and including a reception system, operatively connected to said imaging system, which receives said transmitted imaging signals comprising:

a plurality of antennae; and

a power supply; and

storage means; and

controlling circuitry means operatively connecting the parts of said reception system.

4. (canceled): A system according to claim 3 and including a transceiver component for wireless communication with other systems.

5. (canceled): A system according to claim 3 and including a communications port for direct wire communication with other systems.

6. (canceled): A system according to claim 3 and including:

a communications port for direct wire communication with other systems; and

a transceiver component for wireless communication with other systems.

7. (canceled): A system according to claim 3, and alternative claims 4 and 5 and 6, and including a programmable computer system operatively connected to said reception system and said imaging system, which processes said transmitted imaging signals saved in said storage means and controls said imaging system comprising:

a computer system; and

software programs which process said imaging signal data into various presentation formats; and

software programs to issue instructions to said controlling circuitry means of said imaging system; and

input means; and

transmission means operatively connecting said computer system input means with said storage means of said reception system.

8. (canceled): A system according to claim 7 and including a transceiver

component for wireless communications with said transceiver component of said capsule and said transceiver component of said reception system.

9. (canceled): A system according to claim 7 and including a communications port for direct wire connections with said miniature communications port of said capsule and said communications port of said reception system.

10.(canceled): A system according to claim 7 and including:

a transceiver component for wireless communications with other systems; and

a communications port for direct wire connections to other systems.

11.(canceled): A system according to claim 1 and alternative claim 2, wherein the electromagnetic wave emitter of said ultra-wideband radar sensor system is an ultraviolet frequency light emitting diode and the electromagnetic wave receiver is an ultraviolet frequency sensitive detector and the shell of said capsule is transparent to ultraviolet waves.

12.(canceled): A system according to claim 1 and alternative claim 2, wherein the electromagnetic wave emitter of said ultra-wideband radar sensor system is an infrared frequency light emitting diode and the electromagnetic wave receiver is an infrared frequency sensitive detector and the shell of said capsule is transparent to infrared waves.

13.(canceled): A system according to claim 1, and alternative claim 2, wherein a non-ultra-wideband receiver is substituted for the electromagnetic wave receiver of said ultra-wideband radar sensor system.

14.(canceled): A system according to claim 11, wherein a non-ultraviolet frequency sensitive receiver is substituted for said ultraviolet frequency sensitive detector.

15.(canceled): A system according to claim 12, wherein a non-infrared frequency sensitive receiver is substituted for said infrared frequency sensitive detector.

16.(canceled): A system according to claim 1, and alternative claims 2 through 15, wherein a transmitter is substituted for said transceiver of claim 1.

17.(canceled): A system according to claim 1, and alternative claims 2 through 16, wherein connecting circuitry means that enables signal communication amongst the components of said imaging system is substituted for said controlling circuitry of claim 1.

18.(canceled): A system according to claim 1, and alternative claims 2 through 17, wherein said capsule imaging system device does not include receiving means for imaging signals emitted by said capsule imaging system device.

19.(canceled): A system according to claim 3, and alternative claims 1 and 2 and claims 4 through 18, wherein said reception system includes receiver means to detect and process imaging signals emitted by said capsule imaging system device.

20.(canceled): A system according to claim 1 and alternative claim 2, wherein the electromagnetic wave emitter of said ultra-wideband radar sensor system is an ultraviolet frequency light emitting diode and the electromagnetic wave receiver is a visible light frequency sensitive detector and the shell of said

capsule is transparent to infrared and visible light waves.

21. (twice rejected) A capsule imaging system comprising:

imaging means including an ultra-wideband sensor system for imaging at least a portion of a gastro-intestinal (GI) digestive tract in a subject, by emitting and receiving a plurality of electromagnetic signals at frequencies in the radio wave spectrum above one gigahertz;

a communications means for communication with at least one antenna outside of the GI digestive tract of the subject, including at least one radio transmitter;

a controlling circuit to control a plurality of communication operations by the radio transmitter, and to control at least one operation of the imaging means;

a capsule to enclose the imaging means, communications means, and the controlling circuit; and

a power supply inside the capsule to supply electrical power to the communication means and the imaging means.

22. (twice rejected) A capsule imaging system comprising:

imaging means, including an ultra-wideband sensor system to substantially image a gastro-intestinal (GI) digestive tract inside a subject, by emitting and receiving a plurality of electromagnetic signals at frequencies in the radio wave spectrum above three gigahertz;

a communications transmitter unit, including a radio transmitter;

a controlling circuit to control at least one transmission by the radio transmitter in communication with at least one antenna outside of the subject, and to control at least one operation of the imaging means;

a capsule to enclose the imaging means, the communications transmitter unit, and the controlling circuit; and

a power supply inside the capsule to supply electrical power to the communications transmitter unit and the imaging means.

23. (twice rejected) The capsule imaging system of claim 22, wherein the ultra-wideband sensor system can substantially image a GI digestive tract with at least one emitting antenna and at least one receiving antenna compatible with electromagnetic frequency signals having fundamental frequencies above three gigahertz.

24. (twice rejected) The capsule imaging system of claim 22, wherein the ultra-wideband sensor system can substantially image a GI digestive tract with one antenna capable of functioning as both an emitting antenna and as a receiving antenna, compatible with electromagnetic frequency signals having fundamental frequencies above three gigahertz.

25. (twice rejected) The capsule imaging system of claim 22, wherein the ultra-wideband sensor system images a GI digestive tract with a plurality of

electromagnetic signals having fundamental frequencies substantially between 3.1 gigahertz and 10.6 gigahertz.

26. (twice rejected) The capsule imaging system of claim 22, wherein the communications transmitter unit operates in conjunction with a wearable vest-style garment for the subject having the GI digestive tract to wear as the capsule travels in the GI digestive tract, wherein the wearable vest-style garment includes at least one communication signal receiving antenna to receive a plurality of radio wave signals from the communications transmitter unit.

27. (twice rejected) The capsule imaging system of claim 21, wherein the capsule imaging system includes at least one radio transceiver for communication means for communication with at least one antenna outside the GI digestive tract of the subject.

28. (twice rejected) The capsule imaging system of claim 22, wherein the capsule imaging system includes at least one radio transceiver for communication means for communication with at least one antenna outside the GI digestive tract of the subject.

(ix)EVIDENCE APPENDIX

1."Ultra-wideband Radar Methods and Techniques of Medical Sensing and Imaging", C.N.Paulson, J.T.Chang, C.E.Romero, J.Watson, F.J.Pearce, N.Levin, Oct. 10, 2005.

(x)RELATED PROCEDING APPENDIX

None.

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,725	12/04/2003	John Paul Weirich		4004

7590 01/16/2007

JOHN WEIRICH
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EXAMINER	
KASZTEJNA, MATTHEW JOHN	
ART UNIT	PAPER NUMBER
3739	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Copy

Office Action Summary

Application No.	Applicant(s)	
10/729,725	WEIRICH, JOHN PAUL	
Examiner	**Art Unit**	
Matthew J. Kasztejna	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 21-28 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

(84

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

In response to the amendment filed on October 26, 2006, the current rejections of the claims *stand.* The following new and reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: Copy

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 21-28 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0085994 to Fujita et al. in view of U.S. Patent No. 5,688,555 to Starr.

In regards to claims 21-25 and 27-28, Fujita et al. disclose a capsule imaging system comprising: imaging means for imaging at least a portion of a gastro-intestinal digestive tract in a subject by emitting and receiving a plurality of electromagnetic signals above three gigahertz (see paragraphs 0051-52, 0063 and 0098), a communications means for communication with at least one antenna outside of the GI digestive tract of the subject including at least one radio transmitter (see paragraph 0122); a controlling circuit to control a plurality of communication operations by the radio transmitter, and to control at least one operation of the imaging means (see Figs. 3-6); a capsule to enclose the imaging means, communications means and the controlling circuit (see Fig. 2); and a power supply 21 inside the capsule to supply electrical power

to the communication means and the imaging means (see paragraph 0052). Fujita et al. are silent with respect to the imaging means including an ultra-wideband sensor system at frequencies in the radio wave spectrum substantially between 3.1 and 10.6 gigahertz. Starr teaches of an analogous imaging system and apparatus which implements ultra-wideband radar motion sensors to provide three-dimensional images in real-time. Furthermore, Starr discloses an object of the invention is to provide an imaging system for use in the biological sciences (see Cols. 1-2). It would have been obvious to one skilled in the art at the time the invention was to use an ultra-wideband imager in the apparatus of Fujita et al. to provide an alternate imaging means capable of producing an image having accurate three-dimensional structure localization with minimal distortion as taught by Starr.

In regards to claim 26, Fujita et al. disclose a capsule imaging system, wherein the communications transmitter unit operates in conjunction with a wearable vest-style garment for the subject having the GI digestive tract to wear as the capsule travels in the GI digestive tract, wherein the wearable vest-style garment includes at least one communication signal receiving antenna 4 to receive a plurality of radio wave signals from the communications transmitter unit (see Fig. 1a).

Response to Arguments

Applicant's arguments filed October 26, 2006 have been fully considered but they are not persuasive.

Applicant's arguments with regards to the patentability of the Fujita et al. application are moot, as they do not pertain to the instant application. Applicant should

discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

copy

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Starr teaches of an analogous imaging system and apparatus which implements ultra-wideband radar motion sensors to provide three-dimensional images in real-time. Furthermore, motivation to combine the apparatuses of Fujita et al. and Starr is provided by the fact that Fujita et al. teaches the desirability of using various and alternate imaging means in the endoscopic capsule, and Starr teaches an object of the invention is to provide an imaging system for use in the biological sciences. Furthermore, Starr teaches of an analogous imaging system and apparatus which implements ultra-wideband radar motion sensors to provide three-dimensional images in real-time. It would have been obvious to one skilled in the art at the time the invention was to use an ultra-wideband imager in the apparatus of Fujita et al. to provide an alternate imaging means capable of producing an image having accurate three-dimensional structure localization with minimal distortion as taught by Starr. Thus, as broadly as claimed, the combination of Fujita et al. and Starr meet the limitations of the recited claims.

Applicants states that Fujita et al.'s patent application 2003/0085994 was not published until May 8, 2003 and thus is not prior art. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action: A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. Thus the rejection is valid.

CQ4

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site http://www.uspto.gov in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. CMK

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J. Kasztejna whose telephone number is (571) 272-6086. The examiner can normally be reached on Mon-Fri, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Ultra-wideband Radar Methods and Techniques of Medical Sensing and Imaging

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Ultra-wideband Radar Methods and Techniques of Medical Sensing and Imaging

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ABSTRACT

Ultra-wideband radar holds great promise for a variety of medical applications. We have demonstrated the feasibility of using ultra-wideband sensors for detection of internal injuries, monitoring of respiratory and cardiac functions, and continuous non-contact imaging of the human body. Sensors are low-power, portable, and do not require physical contact with the patient. They are ideal for use by emergency responders to make rapid diagnosis and triage decisions. In the hospital, vital signs monitoring and imaging application could improve patient outcomes. In this paper we present an overview of ultra-wideband radar technology, discuss key design tradeoffs, and give examples of ongoing research in applying ultra-wideband technology to the medical field.

Keywords: Ultra-wideband, UWB, Micro-power impulse radar, medical, hematoma, cardiac, respiratory, imaging

1. INTRODUCTION

Motion sensing and imaging ultra-wideband (UWB) radar systems have strong potential for use in the medical field. UWB radar is non-invasive, low power, and can be manufactured in a small, portable form factor. We have demonstrated the use of UWB radar in a variety of medical applications. A handheld UWB sensor has demonstrated the feasibility of detecting the presence of traumatic internal injuries including intracranial hematoma and pneumothorax. A UWB vital signs monitor tracks cardiac and respiratory motions remotely, without direct skin contact. UWB radar arrays can image the human body. This paper will explore key tradeoffs in the design of ultra-wideband systems for medical applications and provide several examples of research in this area.

1.1. Ultra-wideband Basics

Unlike narrowband systems, which transmit continuous waveforms at a specific frequency, ultra-wideband systems transmit narrow impulse-like signals that span a broad frequency range [Figure 1]. The pulse width of a UWB system is typically within a range of 100's of picoseconds to several nanoseconds, with rise times as fast as 50 picoseconds, corresponding to a frequency range that can span several gigahertz. Since the energy of the pulse is distributed across a many frequencies, the power spectral density is much lower in magnitude than a narrowband system. To a narrowband system, ultra-wideband signals appear below the noise floor, and are therefore very difficult to detect.

UWB signals can be used in many applications, including imaging, vehicular radar, and communications. Examples of imaging applications are ground penetrating radar, through-wall imaging to detect the location or movements of objects, surveillance, search and rescue, and medical systems. Vehicular radar systems are commonly used for collision avoidance and roadside assistance. Ultra-wideband communication systems are useful for high data rate transmission in harsh propagation environments, such as indoor applications with dense multi-path channels, for consumer electronics, and for covert operations.

The FCC defines ultra-wideband signals to be those with fractional bandwidth exceeding 20% of the center frequency, or those with greater than 500 MHz bandwidth[1]. Although development of ultra-wideband technologies began in the

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1960s[2,3], the technology is far from mature. Widespread commercial use has been limited, largely as a result of FCC restrictions. Due to concerns of interference with existing communication and navigation systems, the FCC limits UWB frequency bands and output power. Medical applications are limited to the 3.1 to 10.6 GHz range[1]. Through-wall imaging applications may operate below 960 MHz, or in the 1.99 to 10.6 GHz range[1]. Commercial devices are currently limited in power, restricting the operating range to about ten meters[4]. Further studies are being performed to quantify the interference risks of UWB to conventional platforms[5,6,7]. Prototype systems have been developed at Lawrence Livermore National Laboratory using an experimental license.

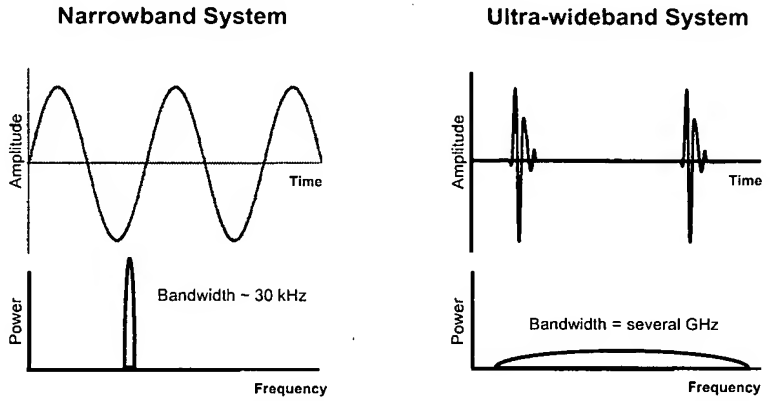

Figure 1: Narrowband vs. UWB in Time and Frequency Domain

1.2. Ultra-wideband Advantages

This section describes the unique advantages that make ultra-wideband systems beneficial for medical use.

1.2.1. Penetrates biological tissues

UWB signals are capable of penetrating a great variety of materials, including plastic, wood, rubber, sheetrock, dry soil, glass, and concrete[8,9,10]. In general, systems with lower center frequencies achieve better material penetration. Biological materials including skin, muscle, fat, and bone can also be penetrated, although not as easily as most low conductivity building materials. Highly conductive materials, such as metals and seawater, cannot be penetrated[4].

1.2.2. Non-invasive, non-contact, and non-ionizing

UWB imaging systems would allow a physician to monitor internal organ movements without invasive surgical procedures. Unlike traditional ultrasound systems, which require direct skin contact, UWB sensors and imaging systems can operate at a standoff distance. Since UWB signals are non-ionizing, they do not cause the adverse effects associated with X-ray systems such as CT scanners. UWB imaging may enable physicians to make a preliminary diagnosis without subjecting the patient to risk or discomfort. In addition, these sensors are well suited for continuous patient monitoring to identify baseline changes.

1.2.3. Low power, portable, and low cost

While a CT scanner provides excellent image specificity, it is large and can cost several hundred thousand to over a million dollars. Handheld UWB sensor prototypes developed at Lawrence Livermore National Laboratory run on a single 9-V battery, and cost only hundreds of dollars to manufacture. Due to their portability and low cost, UWB sensors are ideal candidates for use in rural or remote settings and in-field use by first responders.

2. SENSING WITH ULTRA-WIDEBAND

A family of ultra-wideband sensors known as micro-power impulse radar[11,12] (MIR) was developed at Lawrence Livermore National Laboratory. MIR sensors emit extremely narrow electromagnetic pulses and analyze received reflection signals for characteristic indicators of material boundaries and movements. MIR sensors are safe for medical

use, since UWB signals are non-ionizing and emitted power is very low. In a typical MIR sensor used for medical applications, peak transmit power is 60 milliwatts and average transmit power is 25 microwatts.

The basic components of an MIR radar system include a transmitter, a reflective target, a receiver, and a signal processor [Figure 2]. The transmitter generates a series of short pulses. The shape of transmitted pulses is determined largely by the characteristics of the antenna. At dielectric interfaces, portions of the transmitted pulse reflect back toward the antenna. The receiver uses a range gate to sample the echo signals during a specific time interval corresponding to the round trip time of flight from the transmitter to the target, and back to the receiver[9]. A sensor with a fixed range gate can only detect echo signals from a single radial distance. By sweeping the range gate across a time span, or equivalent time sampling[9], targets can be detected within a specified distance range. Multiple pulses are integrated to achieve a sufficient signal-to-noise ratio. Signal processing of the received pulse echoes may be performed in analog circuitry, using an FPGA, or using software algorithms running on a computer.

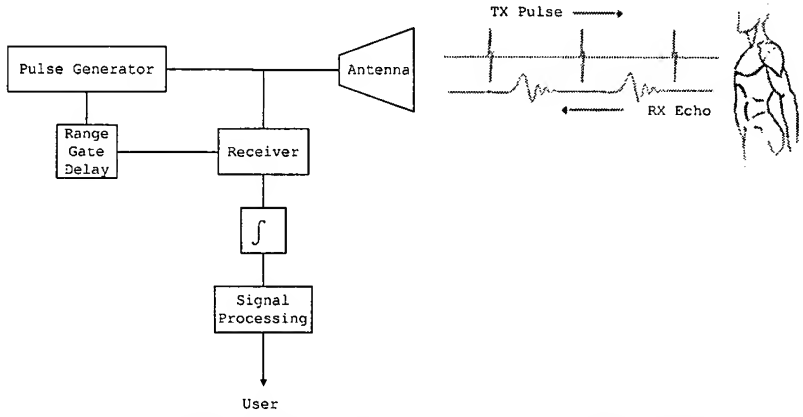

Figure 2: Micro-power Impulse Radar Sensor Block Diagram

2.1. Distance Measurement

One application of UWB radar is to measure the distance between the radar source and a reflective target. Ranging applications are based on measuring the round trip time of flight of a transmitted pulse. For example, if the time between sending a pulse and receiving its backscatter echo is 20 ns, we can infer that the signal was reflected at the target after 10 ns. If the target is in air, we can assume that the pulse velocity, v, is 3.0×10^8 m/s, the speed of light. Using the simple relationship, $d = vt$, we find the reflecting target was positioned 3 meters away from the radar. By sweeping the range gate across a time span of 15 ns to 25 ns, we can detect reflected pulses from targets within a distance range of 4.5 to 7.5 meters.

Distance measurements become challenging when the nature of target mediums is unknown. Since propagation velocity is material dependent, assumptions are made about the electromagnetic properties and thickness of target materials. For example, at 2 GHz, the relative permittivity, ε_r, of muscle and fat are 5.5 and 4.5, respectively[13]. The corresponding propagation velocities are $v_{muscle} = 1.3 \times 10^8$ m/s and $v_{fat} = 1.4 \times 10^8$ m/s, and are found by:

$$v = \frac{c}{\sqrt{\varepsilon_r}}.$$

In several UWB medical applications, ranging sensors are used to identify physical abnormalities or deviations from a baseline, giving only approximate location information. For these applications, knowledge of exact thicknesses and material properties is not required. For example, a quick identification of the presence or absence of internal trauma injuries, such as intracranial hematoma or pneumothorax, can assist medical personnel in making triage and treatment decisions when more sophisticated diagnosis methods are unavailable.

2.2. Motion Detection

To detect motion, one can simply monitor a ranging sensor over time for changes in target position. A derivative circuit and a comparator can be used as a motion indicator. Using swept range radar, it is possible to determine the locations and deflection magnitudes of multiple moving targets. We have demonstrated several medical applications for UWB motion sensing, including monitoring of speech, respiratory, and cardiac motions[4,9,14]. UWB motion detectors have also been used in search and rescue applications, to identify victims trapped in collapsed structures.

2.3. Imaging with Ultra-wideband Sensor Arrays

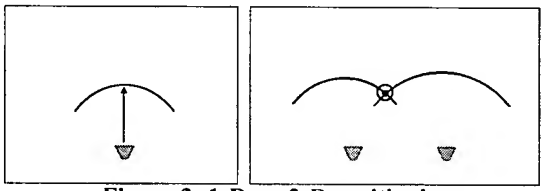

Figure 3: 1-D vs. 2-D positioning

A single UWB ranging sensor can provide position and motion information in one dimension only. While it is possible to detect the radial distance between the radar and a target, a single sensor cannot determine the target angle. If two sensors are used, it is possible to determine the position of a target in two dimensions [Figure 2]. To obtain three-dimensional positioning information, an array of three or more sensors is used. UWB sensor arrays have been used to image a variety of targets, including bridge decks, buried land mines, walls, and the human body.

2.4. Ultra-wideband Radar for Biological Sensing

As UWB signals travel through tissues, their amplitudes attenuate exponentially with the factor $e^{-\alpha z}$, where α is the attenuation constant of the tissue, and z is distance. When signals reach an interface between two mediums with differing dielectric properties, a portion of the signal is transmitted through the boundary, and a portion is reflected. The transmitted and reflected signals are given by:

$$E_t = \tau \cdot E_i \qquad \text{and} \qquad E_r = \Gamma \cdot E_i,$$

where E_i is the incident wave, τ is the transmission coefficient, and Γ is the reflection coefficient. The transmission and reflection coefficients are given by:

$$\tau = \frac{2 \cdot \sqrt{\varepsilon_{r1}}}{\sqrt{\varepsilon_{r1}} + \sqrt{\varepsilon_{r2}}} \qquad \text{and} \qquad \Gamma = \frac{\sqrt{\varepsilon_{r1}} - \sqrt{\varepsilon_{r2}}}{\sqrt{\varepsilon_{r1}} + \sqrt{\varepsilon_{r2}}},$$

where ε_{r1} and ε_{r2} are the relative permittivities of the two mediums.[14,16] By detecting ultra-wideband reflections, sensors can determine the presence or absence of abnormalities at tissue boundaries and monitor their motion.

For sensing biological tissue boundaries, adjacent tissues with differing dielectric properties are easiest to see. To illustrate this point, consider the task of identifying a pneumothorax, or collapsed lung. The relative permittivities of tissues in the chest cavity over typical UWB frequencies are shown [Figure 4]. There is a significant difference between the dielectric properties of an inflated lung compared to a deflated lung. Using the dielectric constants of muscle, inflated lung, and deflated lung at 2 GHz, we find the reflection coefficient at the muscle/inflated lung interface to be $\Gamma_{MIL} = 0.25$, and the reflection coefficient at the muscle/deflated lung interface to be $\Gamma_{MDL} = 0.03$. We can detect the presence of an abnormal condition, such as pneumothorax, by comparing echo signals from a healthy lung to an afflicted lung. The same principles are applied to other UWB medical applications, including cardiac and respiratory monitors, and intracranial hematoma detection.

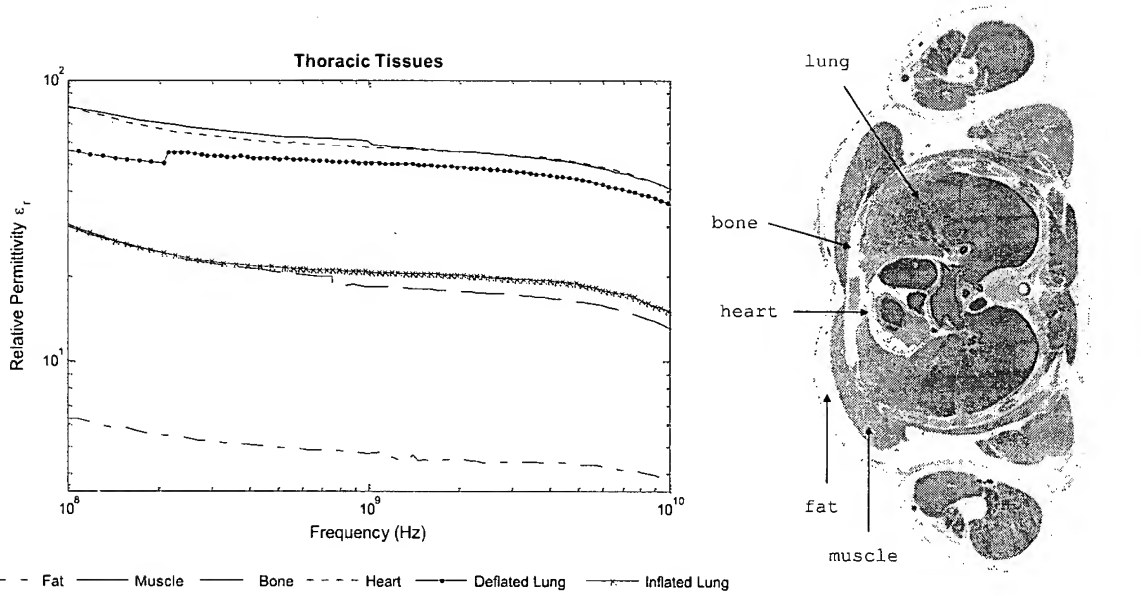

Figure 4: Thoracic Tissues[17] and Dielectric Properties[13]

2.5. Design Variables and Tradeoffs

A designer of an UWB system must make a number of design choices specific to the application. These choices are interrelated, and reveal many tradeoffs in system performance. The following section outlines the key specifications involved in the design of an ultra-wideband sensing or imaging system, including frequency content, power, pulse repetition rate, receiver window size, and receiver integration time.

2.5.1. Frequency Content of UWB Signals

The frequency content of an ultra-wideband signal is specified by its center frequency and its bandwidth. A large bandwidth is beneficial, because many materials can be penetrated while achieving good spatial resolution. Choosing the frequency content of the system has implications for other system parameters. For example, low frequencies are desirable for achieving good penetration through dense materials. To create a lower frequency signals, however, a larger antenna is required, increasing the overall size of the device. High frequency signals yield good specificity, since the measurable spatial resolution is related proportionally to the wavelength. A very large bandwidth, however, can reduce the signal to noise ratio (SNR). For Gaussian noise, the noise power is proportional to signal bandwidth. Therefore, for a fixed signal power, as bandwidth increases, the SNR decreases.

2.5.2. Power

The power characteristics of an UWB system can be described by its instantaneous peak signal power, average signal power, and average system power consumption. A large peak signal power is important for obtaining good penetration through materials and long operating distances. An increase in peak power results in a proportional increase in the SNR. A major drawback, however, is a reduction in the efficiency of high power pulse generation circuits. As average system power consumption increases, the battery life decreases. For very high power systems, there could be concerns for interference with other radiofrequency devices and safety.

2.5.3. Pulse Repetition Rate

The repetition rate of emitted pulses sets an upper limit on the operating distance of UWB sensors. UWB systems measure the time of flight for pulses to reflect off of a target. The pulse repetition rate must be slow enough to allow reflected pulses to return to the receiver; otherwise, transmitted pulses would interfere with received signals. A faster pulse repetition rate improves the responsiveness of motion detection systems, allowing them to recognize high frequency movements such as vocal cord vibrations. To reduce the likelihood of being detected by or causing

interference to narrowband systems and other ultra-wideband systems, randomized noise is added to the pulse repetition interval. This technique also reduces interference from other sources.[9]

2.5.4. Receiver Window Size

A range gate is used to sample received signals at specific time intervals. The receiver window size corresponds to the time window for sampling. Choosing a small window allows greater spatial resolution and better sensitivity to small movements, however, faster sampling circuits are required.

2.5.5. Receiver Integration Time

In order to improve the signal-to-noise ratio of an UWB system, averaging can be used. Instead of examining the received signal from a single pulse, which will be obscured by a number of noise sources, many pulses can be observed, one after another. These received signals are accumulated for some period of time, performing the equivalent of integration or averaging. The average received signal still contains noise, but its effects are greatly reduced. For purely Gaussian noise sources, the effective noise seen by the sensor is reduced by the square root of the number of cycles over which the integration is performed. This increases the operating range and sensitivity, but decreases the speed and responsiveness to motion.

3. MEDICAL APPLICATIONS OF UWB RADAR

The following are examples of ongoing research at Lawrence Livermore National Laboratory and collaborating institutions in the area of ultra-wideband radar technology applied to medical purposes. They illustrate the diversity and adaptability of the technology. Three different measurement techniques are represented: a swept range radar snapshot, motion characterization, and imaging.

3.1. Hematoma Detector

Patients having unrecognized intracranial injuries may develop permanent brain damage, severe disability, or death. Early diagnosis and treatment of intracranial hematomas is essential for improving patient outcomes[17,19]. The current method used to identify intracranial hemorrhage is computed tomography (CT)[20]. Unfortunately, not all head trauma patients have access to this technology. Scanners are large, and therefore restricted to a hospital setting. Many rural hospitals cannot afford CT scanning equipment and support staff. CT scanners are not readily transportable; therefore patients must be transported to a hospital before a diagnosis can be made. This delay in neurosurgical intervention can result in irreversible brain injury or death.

A portable, hand-held hematoma detector could be of use for traumatic brain injury patients in the field to properly triage victims and minimize unnecessary delays before definitive medical intervention. Pre-hospital diagnosis may allow for earlier initiation of neuroprotective brain injury interventions, including operative hematoma evacuation, intracranial pressure monitoring and catheter placement, and drug therapy. Furthermore, such a portable device could screen for neurosurgical mass lesions in the multiple trauma patient too unstable for CT, or for hematomas in the intensive care unit setting. Expedited screening may facilitate the prevention of secondary brain injury consequent to hematoma development.

3.1.1. Prototype Description

A handheld micro-power impulse radar (MIR) prototype device was developed for detection of intracranial hematomas[21] [Figure 5]. This system is based on an ultra-wideband swept range sensor. A swept range radar scans an area in space by varying the time delay between signal launch and capture. Using the propagation velocity, the time of flight can be related to distance. Key specifications are a center frequency of 2 GHz, a 200 ps pulse width, a 2 MHz pulse repetition rate, an average power density of less than 0.001 mW/cm^2, and a peak power density of 2.5 mW/cm^2, measured at a distance of 1cm.

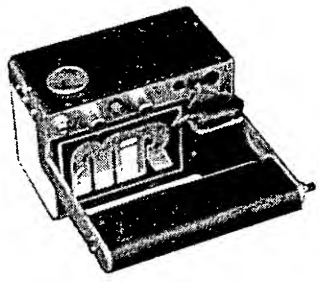

Figure 5: Handheld Hematoma Detector

The concept of operation is to use the inherent bilateral symmetry of the

brain to identify abnormalities. In healthy patients, UWB echo signals from the left and right side of the brain should look very similar. If an injury is present, the signals will differ.

3.1.2. Experiments

The feasibility of hematoma detection with ultra-wideband radar has been tested using laboratory models and limited human subject experiments. The goal of early experiments was to determine whether a correlation exists between the magnitude of a simulated hematoma and UWB echo signals recorded by the MIR sensor. In the laboratory model, a phantom hematoma setup consisted of four pig brains placed inside of a human skull. Known volumes of either blood or air were injected between the skull and the brain tissue. In the human subject experiment, MIR sensor scans were collected from six healthy volunteers and six patients with intracranial injuries. The intracranial abnormalities included chronic subdural hematoma, acute subdural hematoma, acute epidural hematoma, and intracranial air (after hematoma drainage). Signals were analyzed by an individual who was blinded to the conditions of the subjects.

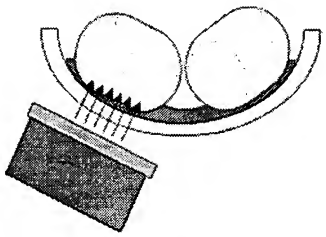

Figure 6: Hematoma Phantom

3.1.3. Results

In laboratory model experiments, characteristic features were observed in UWB echo signals corresponding to reflections from tissue interfaces. As blood was introduced between the skull and brain tissue, signal attenuation and delays were observed in certain characteristic features of the signal. An increasing spatial offset between brain tissue and the skull correlates with echo signal variations. MIR sensor signal returns from the phantom hematoma model with varying volumes of blood are shown [Figure 7]. As expected, reflections from the skull are well aligned for each echo trace. As the blood volume increases, a greater delay is introduced by the slower propagation of the signal through blood. The magnitude of the reflected signal is also decreased by the presence of hematoma.

In human subject experiments, a characteristic UWB echo signal was observed. Bilateral symmetry was confirmed in healthy patients. Delays and attenuations in characteristic features of the signal were observed in patients with hematoma [Figure 8]. A blinded observer correctly classified MIR scans as healthy or containing hematoma, and correctly predicted the location of intracranial abnormalities.

Based on the promising results of the laboratory and human subject experiments, an expanded collaborative study is proposed involving several hospitals and many patients. The goal is to determine whether the MIR sensor can effectively screen blunt head injury patients for urgent neurosurgical intervention.

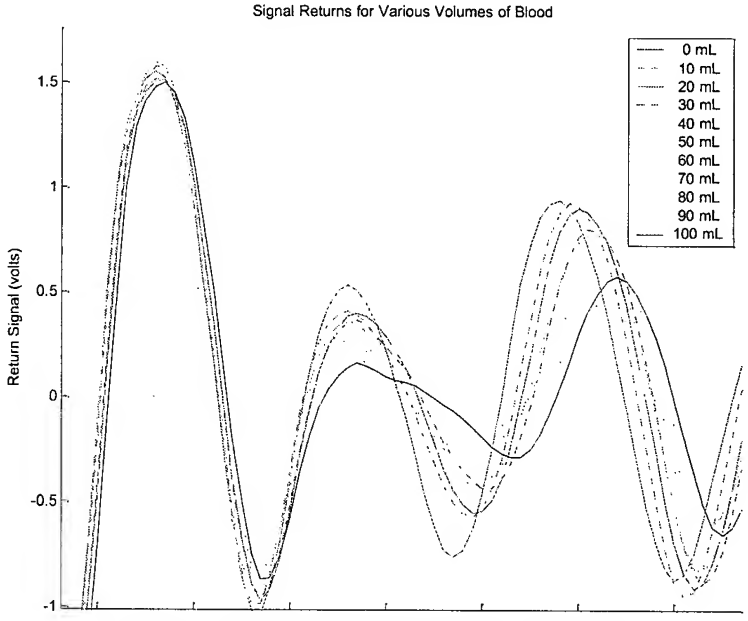

Figure 7: MIR signals from phantom hematoma

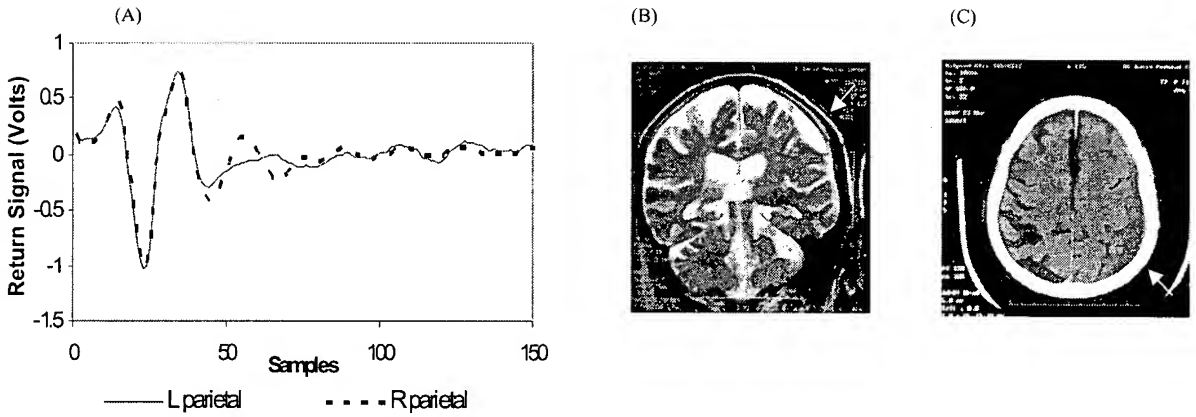

Figure 8: Patient with Chronic Subdural Hematoma – (A) MIR scan (B) CT axial (C) MRI coronal

3.2. UWB Vital Signs Monitors

Continuous, un-tethered monitoring of patient vital signs is not available. The primary tool used in screening for cardiovascular disease is the electrocardiogram (ECG), which records the electrical signals of the heart. It typically requires placement of twelve electrodes on the body. Heart rate monitors are smaller versions of an ECG, which use two or three electrodes to determine the heart rate. Another tool, which is frequently used in hospital settings to detect hypoxia, is the pulse oximeter. As a patient's hemoglobin saturation drops, blood becomes bluer in color. A pulse oximeter measures the amount of oxygen in a patient's blood by observing light reflections. As blood vessels expand and contract with every heart beat, the pulse oximeter signal fluctuates. The pulse oximeter probe requires direct contact with the finger or ear lobe. The stethoscope is an acoustic tool that enables physicians to listen to heart sounds and breathing. All of these tools require direct patient contact.

UWB sensors could provide a continuous, non-contact technique for cardiac and respiratory assessment that would be beneficial for minimizing patient disruption. Hourly collection of vital signs is perceived to be a leading cause of sleep deprivation in intensive care unit patients[21]. Studies have shown that sleep deprivation can slow the healing process by impairing protein synthesis, cell division, and cellular immunity[23]. Another application for non-contact vital signs monitoring may be in patients with chronic kidney disease. Sudden cardiac death accounts for about half of outpatient dialysis deaths[24]. Nursing staff must closely monitor patient vital signs for any irregularities. A continuous, non-contact cardiac and respiratory monitoring device may improve patient care without causing discomfort to patients. Because no human contact is required, the device would not require cleanings or sterilization. An ultra-wideband motion detection device could accurately monitor cardiac and respiratory movements, and could simply be mounted on the back of a chair or bed.

Due to its portability and low cost, UWB technology may be beneficial for use by first responders and medical personnel in remote areas. In field operations, a portable non-contact vital signs monitor could be useful for preliminary diagnostics and triage. Battlefield medics could use UWB cardiac monitors when an ECG was not available. Sensors could be worn by soldiers or firefighters in dangerous situations and monitored remotely. A sensor that can penetrate common building materials to detect respiration and body movement would be useful in search and rescue operations to identify live victims in burning buildings or collapsed structures. Other proposed applications include monitoring for Sudden Infant Death Syndrome and sleep apnea.

3.2.1. Prototype Description

Cardiac and respiratory monitoring has been achieved using the same hardware as described for hematoma detection [Section 3.1.1]. The primary differences are in signal processing. Instead of taking a snapshot, pulse echo signals are monitored continuously for signal changes in time. By differencing subsequent scans, motion can be identified. Filters

can be used to target specific respiratory or cardiac frequencies. Swept range radars are used to generate intensity or waterfall plots as a function of time and depth. Fixed range sensors monitor changes in signal intensities a fixed distance from the radar.

3.2.2. Experiments

Vital signs were collected from 40 human volunteers at Walter Reed Army Institute of Research using a micro-power impulse radar range finding prototype. Readings from an ECG and pulse oximeter were captured simultaneously with MIR readings. These traditional sensor technologies were used to confirm MIR signal features were well correlated with respiration and cardiac events. MIR sensor readings were collected from each volunteer in four different body positions: standing upright, lying face up, lying on the right side, and lying face down. Since the readings of the MIR range finder prototype correspond to reflections off of tissue interfaces, rather than electrical impulses as in the ECG, body position was expected to be an important factor. Volunteers were asked to breathe slowly, while readings were captured for 60 seconds.

In another experiment, fixed range radar signals were compared to ECG, cardiac impedance, and acoustic heart signals to determine how well characteristic features of MIR signals could be related to traditional sensor technologies. Further experimentation needs to be performed in order to correlate radar signals to heart motions, such as cardiac contractions and arterial wall movements. Expanded human subject studies could reveal whether the MIR prototype has a high enough degree of sensitivity and specificity to detect the presence of cardiac arrhythmia or damage to the heart muscle.

3.2.3. Results

Using the range finding MIR prototype, the human respiration and cardiac cycle can be clearly identified. A depth scan is shown as an intensity plot, where the Y-axis can be interpreted as depth (distance from the radar) and the X-axis is time [Figure 9]. Intensity corresponds to the magnitude of the received signal. Low frequency undulations correspond to slow respiration, while high frequency features correspond to heart motion. ECG and pulse oximeter traces are well correlated with the periodic features seen in the MIR depth scan.

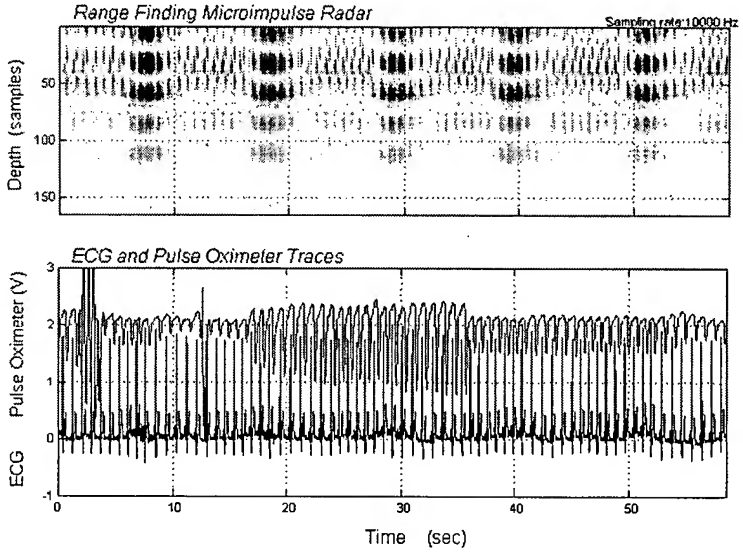

Figure 9: UWB Vital Signs Monitor, ECG and Pulse Oximeter Signals from Human Volunteer

Return signals from the fixed range sensor also correlate well with traditional cardiac monitoring methods. A comparison of traces from the ultra-wideband radar, impedance sensor, acoustic sensor, and ECG are shown [Figure 10]. We have demonstrated the feasibility of using ultra-wideband technologies to monitor cardiac and respiratory

motions; however more investigation is required to understand the relationship between UWB radar signals and advanced cardiac functions. UWB Radar provides information about a fundamentally different phenomenon than an ECG; it is related to the actual motions of the heart muscle rather than its electrical impulses. Therefore, it is conceivable that UWB radar technology may reveal diagnostic capabilities not readily available in traditional methods.

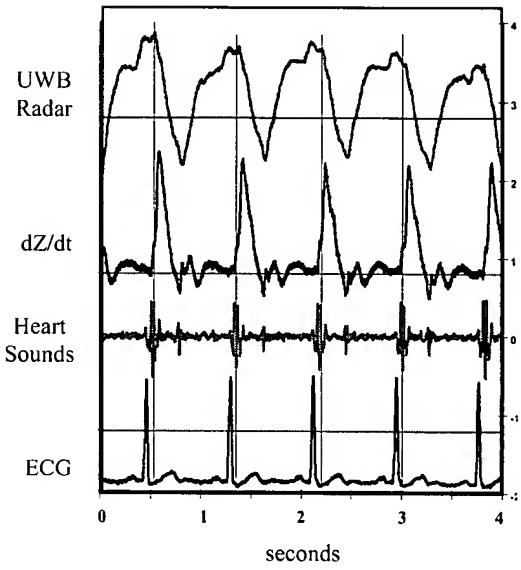

Figure 10: Comparison of UWB Cardiac Signals to Traditional Methods

3.3. Ultra-wideband imaging of the human body

Traditional techniques for imaging the human body include ultrasound, magnetic resonance imaging (MRI), computed tomography (CT), and traditional x-rays. UWB imaging may provide a means of long term continuous monitoring of the human body that cannot be accomplished using traditional techniques. CT scanners and x-rays emit ionizing radiation, and exposure should be minimized. Ultrasound requires direct skin contact, and is therefore suited for short term monitoring only. Magnetic resonance imaging is not practical for long term continuous monitoring because the mechanics of the instrument surround the patient. Also, metallic objects are prohibited, which excludes individuals with a surgical prosthesis or pace maker.

An UWB imaging instrument does not emit ionizing radiation, does not require patient contact, and can be operated at a standoff distance, and therefore may be suitable for long term, continuous monitoring purposes. Such an instrument could be useful for monitoring a patient in a hospital bed, as an alternative to CT or MRI when a patient is not stable enough to be relocated, or for real-time imaging of organs. Also, embedded metallic objects are easily identified.

3.3.1. Prototype Description

The imaging instrument consists of a phased array of swept range UWB radar sensors. A digital timing and data acquisition system is used to control the launch and capture times of each sensor. The system is electronically reconfigurable, such that the size and resolution of the scanned volume can be adjusted. The achievable resolution is related to the frequency content of the radar elements and the array aperture. The signal to noise ratio is given by both the number of elements and their spatial distribution, as well as the standoff distance. Simulations suggest that a resolution of 1 cm can be obtained for targets positioned at a 1-meter standoff with an array of 48 sensors spanning a 1-meter by 1-meter aperture. Raw data for a 200x200 pixel image is captured at 20 frames per second. Using tomographic reconstruction algorithms, a two-dimensional image is created from scans of a volume in space. Images are reconstructed in post-processing on a separate computer. A field programmable gate array (FPGA) implementation to carry out the image reconstruction is currently under development. We estimate the FPGA system will be capable of processing four reconstructed images per second at the output quality exhibited by Figure 11.

3.3.2. Experiments

A preliminary experiment used an UWB radar array to scan a 1-meter by 2-meter by 0.5-meter volume. Human volunteers were imaged at a standoff distance of one meter. To simplify the experiment, the human subjects were scanned in front of radar absorbent foam.

3.3.3. Results

Constructed images show recognizable human features. A female and a male subject are shown [Figure 11]. The male was wearing a metallic belt buckle, which appears as a highly reflective object. The image of the female is 300x220 pixels. Each pixel corresponds to 0.6-cm. The image of the male is 485x320 pixels. Each pixel corresponds to 0.4-cm.

Although these results do not demonstrate the sub-millimeter specificity of an MRI or CT scan, higher resolutions could be obtained through the use of a higher frequency radar or a greater number of radar elements. Ultra-wideband radar imaging has potential to be a viable patient monitoring technology. Key advantages that satisfy specific application needs not addressed by MRI or CT include real-time imaging of moving organs, inexpensive hardware, and portability.

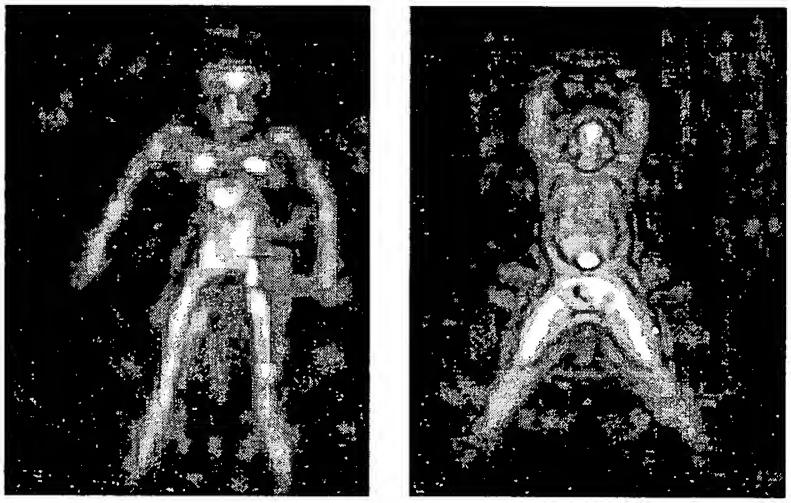

Figure 11: UWB radar images of human volunteers. Female (left) Male (right)

4. CONCLUSION

Ultra wideband radar is a flexible technology that can be adapted to a variety of medical applications. A suite of Micro-power Impulse Radar technologies have been developed at Lawrence Livermore National Laboratory. Prototype devices have the ability to detect internal tissue boundaries, monitor motion, and produce images without direct contact with a patient. They are low-power, safe, portable, and inexpensive. Through the selection of design parameters, UWB radar systems can be tailored to achieve high performance for specific applications. We have demonstrated the feasibility of MIR devices for use in detection of internal injuries, such as hematoma. The hand-held form factor, low power requirement, and rapidly generated results make this detector suitable for use in remote areas, where CT and MRI imaging systems are unavailable. Another adaptation of an MIR sensor was used to monitor respiratory and cardiac motion in human subjects. Potential applications include use by first responders for diagnosis and triage and unobtrusive vital signs monitoring in hospitals and dialysis clinics. Multiple radar sensors can be combined in a phased array and used to scan a three-dimensional volume for imaging purposes. Preliminary experiments show successful tomographic reconstruction of UWB signals for imaging human subjects. Unlike CT and MRI systems, ultra-wideband radar could be used for continuous, real-time monitoring over extended time periods. These examples demonstrate only a few possibilities for this promising technology.

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6. REFERENCES

1. *Code of Federal Regulations: Part 15 Subpart F Ultra-Wideband Operation.* Federal Communications Commission. May 2002.
2. T.Barret, "History of UltraWideBand (UWB) Radar & Communications: Pioneers and Innovators", Progress in Electromagnetics Symposium, Cambridge, MA, July 2000
3. R.J.Fontana. "Recent System Applications of Short-Pulse Ultra-Wideband (UWB) Technology" *IEEE Transactions on Microwave Theory and Techniques.* Vol.52 No.9. Sept 2004
4. S.Azevedo, "Exploring the Ultrawideband" *Science and Technology Review.* UCRL-TR-52000-04-9. Sept 2004.
5. J.R.Hoffman, M.G.Cotton, R.J.Achatz, R.N.Statz, R.A.Dalke "Measurements to Determine Potential Interference to GPS Receivers from Ultrawideband Transmission Systems" *NTIA Report 01-384.* February 2001
6. J.E.Padgett, J.C.Koshy, A.A.Triolo, "Physical-Layer Modeling of UWB Interference Effects" *DARPA NETEX Program MDA972-02-C-0056.* Jan 2003.
7. J.R.Fontana, "An Insight Into UWB Interference From a Shot Noise Perspective" *IEEE Conference on Ultra Wideband Systems and Technologies* Baltimore, MD. May 2002
8. A.Safaai-Jazi, S.M.Riad, A.Muqaibel, A.Bayram. "Ultra-wideband Propagation Measurements and Channel Modeling: Report on Through-the-Wall Propagation and Material Characterization" *DARPA NETEX Program.* Nov 2002. Sept 2005. http://www.darpa.mil/ato/programs/netex/models.pdf
9. S.G.Azevedo and T.E. McEwan, "Micropower Impulse Radar" *Science and Technology Review,* UCRL-52000-96-1/2, Jan. 1996
10. R.Dilsavor, W.Ailes, P.Rush, F.Ahmad, W.Keichel, G.Titi, M.Amin. "Experiments on wideband through the wall imaging." *Proceedings of the SPIE Defense & Security Symposium, Conference on Algorithms for Synthetic Aperture Radar Imagery XII,* Orlando, FL, March 2005
11. T.McEwan, "Ultra-Wideband Radar Motion Sensor". U.S. Patent 5,361,070, Nov. 1, 1994
12. T.McEwan, "Impulse Radar with Swept Range Gate". U.S. Patent 5,805,110, Sept. 8 1998
13. C.Gabriel, "Compilation of the Dielectric Properties of Body Tissues at RF and Microwave Frequencies" *Brooks Air Force Technical Report AL/OE-TR-1996-0037.* Appendix D. June 1996
14. J.Mast, S.Azevedo, W.Haddad, L.Ng, G.Burnett, "Micropower Impulse Radar Technology and Applications" *Lawrence Livermore National Laboratory Technical Report UCRL-ID-130474.* Apr. 1998
15. S.J.Orfanidis. *Electromagnetic Waves and Antennas.* Ch.2, Ch.4. June 2004 <http://www.ece.rutgers.edu/~orfanidi/ewa>
16. S.Ramo, J.R.Whinnery, T.Van Duzer. *Fields and Waves in Communication Electronics.* pp270-316.John Wiley & Sons USA. 1984
17. *Visible Human Project.* US National Library of Medicine. National Institutes of Heath. Sept 2003. <http://www.nlm.nih.gov/research/visible/>
18. P.E.Stieg, C.S.Kase. "Intracranial hemorrhage: diagnosis and emergency management." *Neurology and Clinical Neurophysiology.* pp273-290. May 1998
19. KY.Willman, DE.Bank, M.Senac, DL.Chadwick. "Restricting the Time of Injury in Fatal Inflicted Head Injuries". *Child Abuse & Neglect.* pp929-940. Oct. 1997
20. CS.Zee, JL.Go, "CT of Head Trauma" *Neuroimaging Clinics of North America.* pp525-539. Aug 1998
21. W.Haddad, J.Chang, T.Rosenbury, G.Dallum, P.Welsh, D.Scott, D.Duarte, V.Acevedo-Bolton. "Microwave Hematoma Detector for the Rapid Assessment of Head Injuries" *Lawrence Livermore National Laboratory Technical Report UCRL-ID-137901.* Feb 2000
22. N.S.Freedman, N.Kotzer, R.J.Schwab. "Patient Perception of Sleep Quality and Etiology of Sleep Disruption in the Intensive Care Unit" *American Journal of Respiratory and Critical Care Medicine.* Vol 159. No.4. pp1155-1162. Apr. 1999
23. S.L.Krachman, G.E.D'Alonzo, G.J.Criner. "Sleep in the Intensive Care Unit" *Chest.* Vol 107. pp1713-1720. Oct 2005
24. C.A. Herzog, Q.Fan, A.J.Collins. "Epidemiology of Sudden Cardiac Death in Dialysis Patients in the United States, 1991-2001" *American Society of Nephrology: USRDS Renal Week 2004.* St. Louis, MO Oct 2004.